UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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IN RE
GPC BIOTECH AG
SECURITIES LITIGATION

MEMORANDUM DECISION

07 Civ. 06728 (DC)

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CHIN, District Judge

In this securities litigation, lead plaintiff Axxion S.A. Luxemburg ("Axxion") and plaintiff Agamemnon Chua ("Chua") allege that defendants GPC Biotech AG ("GPC") and certain of its officers made material misrepresentations and omissions concerning GPC's application to the Food and Drug Administration (the "FDA") for "fast track" approval of its experimental anti-

cancer drug, Satraplatin. On February 13, 2009, I denied defendants' motion to dismiss the consolidated class action complaint (the "complaint"). See In re GPC Biotech AG Sec. Litig. (GPC I), 597 F. Supp. 2d 412 (S.D.N.Y. 2009). In doing so, I relied heavily on the allegations in the complaint that (1) the FDA had "no experience" with "progression free survival" ("PFS") as an endpoint in clinical studies (see, e.g., Compl. ¶ 17), and (2) the FDA told GPC that it would not accept PFS as an endpoint in GPC's clinical study for Satraplatin (id. ¶ 12). See GPC I, 597 F. Supp. 2d at 423.

As it turned out, these allegations were incorrect. On March 3, 2009, defendants moved for reconsideration. At a conference on March 11, 2009, plaintiffs' counsel acknowledged that the allegations were incorrect and conceded that the complaint could not be sustained if the allegations were deleted. Consequently, on March 12, 2009, I vacated my February 13, 2009, opinion and granted defendants' motion to dismiss. Plaintiffs asserted that they would be able to file an amended consolidated class action complaint (the "amended complaint") that would state a cause of action even with the critical allegations deleted, and thus I permitted plaintiffs to move for leave to file an amended complaint.

Plaintiffs' motion for leave to file an amended complaint is now before the Court. Defendants oppose the motion. For the reasons set forth below, plaintiffs' motion for leave to amend is denied.

BACKGROUND

A. Facts

The facts are set out in the amended complaint. The facts are similar to those set forth in the complaint, which are summarized in GPC I, 597 F. Supp. 2d at 415-20, and thus the facts set forth there are incorporated by reference and will not be repeated here. The principal differences between the complaint and the amended complaint are as follows:

The complaint alleged that GPC falsely represented to the public that an agreement had been reached with the FDA that PFS could serve as the primary endpoint for the SPARC trial. Indeed, GPC's April 3, 2006, annual report stated: "As agreed with the FDA and the European Medicines Agency . . . the primary endpoint for the SPARC trial is progression-free survival." See id. at 423. Plaintiffs alleged that this statement was false because there was no agreement with the FDA on the use of PFS. To the contrary, the complaint alleged that the FDA told GPC that PFS would not suffice as the study's primary endpoint. (Compl. ¶¶ 12-14).[1] The complaint also alleged that the FDA had had "no experience with" PFS as an endpoint (id. ¶ 12), and that GPC issued overly optimistic press releases that should have

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[1] "Compl." refers to the complaint. "Am. Compl." refers to the amended complaint. "Pl. Leave Mem." refers to plaintiffs' memorandum of law in support of their motion for leave to file a consolidated amended class action complaint. "Def. Mem." refers to defendants' memorandum of law in opposition to plaintiffs' motion for leave to amend.

disclosed the FDA's lack of experience with PFS as an endpoint. See GPC I, 597 F. Supp. 2d at 423-24.

These allegations have been deleted from the amended complaint. Instead, plaintiffs allege in the amended complaint that "[from the very beginning, . . . [d]efendants understood that there were serious obstacles standing in the way of FDA approval." (Am. Compl. ¶ 7). Plaintiffs allege that in the discussions with the FDA, GPC sought to convince the FDA to permit use of PFS as a measure of success, while the FDA expressed its preference for designing clinical trials to measure "Overall Survival" as opposed to PFS. (Id. ¶¶ 9-10). Instead of alleging that the FDA had told GPC that PFS would be unacceptable as a primary endpoint because the FDA had no experience with PFS (Compl. ¶ 17), in the amended complaint plaintiffs allege that the FDA stated that it had no experience with "GPC's use of PFS as a primary endpoint." (Am. Compl. ¶ 17 (emphasis added)).[2] Plaintiffs further allege that, after much debate, the FDA allowed GPC to proceed with the SPARC trial using PFS as defendants had requested, but only if GPC added Overall Survival to the trial protocol. (Id. ¶ 11). Plaintiffs contend that in

[2] In their memorandum of law, plaintiffs explain that "[p]laintiffs realized what the FDA meant by stating that it had 'no experience' with the PFS endpoint: The FDA meant that it had no experience with the PFS endpoint as GPC defined it, or with some of the tests [d]efendants proposed using to show that the drug would effectively slow down the progress of prostate cancer in patients given the drug. Based on this newly discovered information, Lead Counsel at this time concluded that the FDA's statement that it had 'no experience' with the PFS endpoint was not meant to be taken literally." (Pl. Leave Mem. at 10).

their subsequent public statements, defendants created the impression that the trials were going well, without disclosing the concerns raised by the FDA as to use of PFS as an endpoint. (Id. ¶ 13).

B. Procedural History

On July 26, August 6, and August 23, 2007, three class actions were filed in this Court alleging that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. In all three cases, plaintiffs sued on behalf of a class of persons who purchased or otherwise acquired GPC securities from December 5, 2005, through July 24, 2007, and who suffered damages as a result. On January 8, 2008, I issued a memorandum decision consolidating the three actions, appointing Axxion as lead plaintiff, and approving Axxion's choice of counsel. See Corwin v. Seizinger, Nos. 07 Civ. 6728, 7016, 7476 (DC), 2008 WL 123846 (S.D.N.Y. Jan. 8, 2008).

On March 12, 2008, Axxion filed the complaint against GPC and the individual defendants. Specifically, plaintiffs alleged violations of Section 10(b) and Rule 10b-5 by GPC, Seizinger, and Scherer. The complaint also alleged that the other individual defendants violated Sections 20(a) and 20A.

On May 15, 2008, defendants moved to dismiss the claims asserted against them. Defendants challenged allegations in the complaint that the FDA has "no experience" with PFS, the endpoint used in the SPARC trial. After plaintiffs reviewed defendants'

reply brief, plaintiffs "concluded that [d]efendants' contention that the FDA's statement that it had 'no experience' with the PFS endpoint was not to be taken literally." (Pl. Leave Mem. at 5). Plaintiffs then suggested that they file an amended complaint, and defendants opposed. (Id.).

On September 5, 2008, Lead Counsel wrote a letter to the Court seeking confirmation of its right to file an amended complaint. (4/1/09 Goldman Decl. Ex. E). Defendants responded in a letter to the Court dated September 17, 2008, contending that leave of the Court was required and that the Court should deny plaintiffs' request. (Id. Ex. F). On September 22, 2008, the Court endorsed the September 5th letter stating that it construed plaintiffs' September 5, 2008, letter as a request for leave to file an amended complaint and denied the request because defendants' motion to dismiss was pending. The memorandum endorsement was docketed September 23, 2008.

In the meantime, plaintiffs sent the Court another letter, dated September 22, 2008, requesting further consideration of its request for leave to amend the complaint. (Id. Ex. G). The Court did not receive the letter until September 23, 2008. On September 24, 2008, the Court endorsed the letter, explaining that plaintiffs' September 22, 2008, letter had arrived after the Court issued its prior order, but noting that the September 22nd letter would be taken into account when the Court decided defendants' pending motion. Specifically,

the Court denied plaintiffs' request to amend as follows:

> The Court will take this letter into account when it decides defendants' pending motion. There is no need for an amended complaint to be filed now if the only change is the removal of the assertion that the FDA had never approved "use of the PFS endpoint as an endpoint for the clinical trial."

On February 13, 2009, the Court denied defendants' motion to dismiss. See GPC I, 597 F. Supp. 2d 412 (2009). In ruling on defendants' motion, the Court did not recall plaintiffs' September 22, 2008, letter or its memorandum endorsement of that letter. The Court relied on the two central allegations of the complaint -- that defendants made material misrepresentations in falsely stating that the FDA had agreed to the use of the PFS endpoint for the SPARC trial and material omissions in failing to disclose that the FDA had no experience with the PFS endpoints. This reliance was in error, as these were the very allegations that the Court had acknowledged on September 24, 2008, it would not rely on.

On February 18, 2009, defendants asked plaintiffs to notify the Court that it had relied on false allegations. (4/1/09 Goldman Decl. Ex. J). By letter dated February 19, 2009, plaintiffs advised defendants that they declined to do so. (Id. Ex. K). Plaintiffs explain now that "they had no reason to believe" that the Court did not take the September 2008 letters into consideration. (Pl. Leave Mem. at 6).

On March 3, 2009, defendants moved for reconsideration of the Court's decision as reflected in GPC I. On March 4, 2009,

defendants sent a letter to the Court advising the Court that they had moved for reconsideration and requesting a pre-motion conference to discuss proposed motions to deny class certification and to stay discovery. (4/1/09 Goldman Decl. Ex. L). On March 4, 2009, the Court issued an order recognizing that it had overlooked the September 22, 2008, letter and directing plaintiffs to respond to the motion for reconsideration. On March 11, 2009, the Court held a conference with counsel for plaintiffs and defendants. At the conference, plaintiffs' counsel acknowledged that the factual allegations in question were incorrect and that the complaint could not be sustained if these factual allegations were deleted. Accordingly, the Court issued its order of March 12, 2009, vacating GPC I, granting defendants' motion to dismiss, dismissing the complaint, and setting forth a schedule for plaintiffs to move for leave to file the amended complaint.

This motion followed.

DISCUSSION

A. Standard for Leave to Amend

Rule 15(a) of the Federal Rules of Civil Procedure provides that where leave of court is required for a party to amend its pleading, "leave shall be freely given when justice so requires." Fed. R. Civ. P. 15(a). Amendments are generally favored "'to facilitate a proper decision on the merits.'" Foman v. Davis, 371 U.S. 178, 182 (1962) (quoting Conley v. Gibson, 355 U.S. 41, 48 (1957)). The decision to grant leave to amend is

within the sound discretion of the trial court. Cresswell v. Sullivan & Cromwell, 922 F.2d 60, 72 (2d Cir. 1990). Leave to amend may be denied for "good reason," including undue delay, bad faith, dilatory motive, prejudice to the opposing party, or the futility of the proposed amendment. Holmes v. Grubman, 568 F.3d 329, 334 (2d Cir. 2009); see Foman, 371 U.S. at 182; Posadas de Mexico, S.A. de C.V. v. Dukes, 757 F. Supp. 297, 300 (S.D.N.Y. 1991) (leave to amend should be granted unless the motion is product of bad faith or dilatory motive, will prejudice opposing party, or be futile); Fustok v. Conticommodity Servs., Inc., 103 F.R.D. 601, 603 (S.D.N.Y. 1984). In the absence of these factors, substantial delay in seeking amendment does not alone warrant denial. See Richardson Greenshields Sec., Inc. v. Lau, 825 F.2d 647, 653 n.6 (2d Cir. 1987).

B. Application

I consider the length of and reasons for the delay, the prejudice to defendants, and the futility of the proposed amendment.

1. Delay

Plaintiffs seek leave to amend their complaint on the grounds that it was not until after defendants' motion to dismiss was fully briefed that they realized "that the FDA's statement that it had 'no experience' with the PFS endpoint was not meant to be taken literally." (Pl. Leave Mem. at 10). Defendants argue that plaintiffs were on notice prior to the completion of motion practice that the allegations in question were false.

The record is clear that plaintiffs knew or should have known, well before the completion of briefing on the motion to dismiss, that their critical allegations were false. Defendants notified plaintiffs of the inaccuracies in the complaint on at least five occasions via letter before plaintiffs sought leave to amend. (See Def. Mem. at 4-5 (detailing defense counsel's efforts to notify plaintiffs' counsel of inaccuracies in complaint)). Plaintiffs do not deny this. Instead, plaintiffs argue that they did not take action on defendants' warnings because defendants refused to provide them with the proper evidence. It was not defendants' responsibility, however, to provide plaintiffs with evidence to prove or disprove the allegations of plaintiffs' own complaint. See Masters v. Wilhelmina Model Agency, Inc., No. 02 Civ. 4911, 2003 WL 1990262, at *4 (S.D.N.Y. Apr. 29, 2003) ("[P]laintiffs have the responsibility to plead their case adequately, without defendants' or the Court's assistance."). Furthermore, the evidence plaintiffs sought from defendants -- a transcript of a meeting of the FDA's Oncology Drugs Advisory Committee ("ODAC") of July 24, 2007 -- was publicly available on the FDA's website from as early as September 21, 2007, almost six months before plaintiffs filed the complaint. (Sheives Aff. ¶ 4 & Ex. B). Plaintiffs' counsel could have -- and should have -- found the ODAC transcript well before they drafted and filed the complaint, and certainly before completion of the briefing of defendants' motion to dismiss. Indeed, it was not reasonable for plaintiffs

to file allegations of securities fraud based on their characterizations of what transpired at an ODAC meeting without first reviewing a publicly available transcript of that meeting.

The delay in these cases has been both substantial and undue. The original cases were filed in the summer of 2007. Now, well more than two years later, plaintiffs seek to file a new pleading, with key factual allegations deleted. Plaintiffs' explanations for failing to uncover their errors earlier are not satisfactory, and much of the delay could and should have been avoided. While I do not reach defendants' contentions that plaintiffs (and their counsel) acted in bad faith and in violation of Rule 11, I do conclude that the delay is largely the fault of plaintiffs. See MacDraw, Inc. v. CIT Group Equip. Fin., Inc., 157 F.3d 956 (2d Cir. 1998) ("district court plainly has discretion to deny leave to amend 'where the motion is made after an inordinate delay, no satisfactory explanation is made for the delay, and the amendment would prejudice the defendant'" (quoting Cresswell v. Sullivan & Cromwell, 922 F.2d 60, 72 (2d Cir. 1990))).

2. Prejudice

Defendants would be prejudiced if plaintiffs were permitted to file an amended pleading now. Defendants have spent considerable resources defending against charges that plaintiffs now acknowledge were false in material respects. Even after defendants advised plaintiffs that critical allegations in the complaint were incorrect, plaintiffs did not take action to

investigate until after defendants' motion was fully briefed. (See Pl. Leave Mem. at 5 ("Lead Counsel elected to re-open its investigation" based on arguments in and exhibits attached to defendant's reply memorandum)). The allegations should never have been made, and, at a minimum, they should have been withdrawn much earlier. Yet, defendants were required to defend against them. If plaintiffs were permitted to file the amended complaint now, resolution of the case would be further substantially delayed. While the expenditure of time and resources, alone, usually will not constitute sufficient prejudice to warrant deviating from the general rule that leave to amend shall be freely granted, see Monahan v. N.Y. City Dep't of Corr., 214 F.3d 275, 284 (2d Cir. 2000), in the unusual circumstances here, and given the inordinate length of the delay, I conclude that defendants would be prejudiced if leave to amend were to be granted.

3. Futility

The Court's prior decision rested almost entirely on two allegations in the complaint that proved to be inaccurate: (1) defendants falsely stated that the FDA agreed to the use of PFS as the primary endpoint for the SPARC trial and (2) defendants failed to disclose that the FDA had no experience with PFS as an endpoint. Indeed, in initially denying defendants' motion to dismiss, I held that:

> the misrepresentations and omissions are material as a reasonable investor could have found the absence of an agreement with the

> FDA and/or the FDA's lack of experience with the chosen endpoint important in deciding whether to invest in GPC. A "substantial likelihood" exists that GPC's disclosure of the absence of an agreement and/or the FDA's inexperience with the PFS endpoint "would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available."

GPC I, 597 F. Supp. 2d at 424 (quoting TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976)).

These two assertions have been deleted from the amended complaint. Without these primary allegations, as plaintiffs have acknowledged, the complaint fails to state a claim upon which relief can be granted. The question before the Court is whether, with the new allegations that plaintiffs seek to substitute in place of the deleted allegations, the amended complaint would adequately state a claim of securities fraud.[3] If not, plaintiffs' motion for leave to amend should be denied on grounds of futility. See Aniero Concrete Co. v. N.Y. City Const. Auth., Nos. 94 Civ. 9111, 95 Civ. 3506, 1998 WL 148324, at *7 (S.D.N.Y. Mar. 30, 1998) ("In addressing the proposed futility of an amendment, the proper inquiry is comparable to that required upon a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6)." (internal quotation marks and citation omitted)). I conclude that the amended complaint, with the critical original allegations replaced by the new allegations, fails to state a claim of securities fraud.

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[3] The pleading standards applicable to securities fraud cases are set forth in GPC I and are incorporated by reference. 597 F. Supp. 2d at 420-26.

In denying defendants' motion to dismiss, I found most troubling plaintiffs' allegation that defendants had falsely represented that the FDA had agreed that PFS could serve as the primary endpoint for the SPARC trial. See 597 F. Supp. 2d at 423. If defendants had stated that the FDA had agreed when it actually had not agreed, surely this would have been the type of clear and egregious misrepresentation that would support a fraud claim. Now, incredibly, plaintiffs would allege the opposite: "the FDA allowed GPC to proceed with the SPARC trial measuring PFS as [d]efendants sought." (Am. Compl. ¶ 11).

Plaintiffs argue that the fundamental premises of the complaint and the amended complaint are identical. Not so. The nature of the alleged fraud has changed fundamentally. What would have been a clear fraudulent statement -- representing there was an agreement when there was no agreement -- has become a much fuzzier representation that is more in the nature of, at worst, mere puffery -- "creat[ing] the impression that the trial was going well" when there were "serious obstacles standing in the way of FDA approval." (Am. Compl. ¶¶ 7, 13). Of course, reasonable investors would have known and expected there to be "serious obstacles" to approval of a new and experimental anti-cancer drug, and the failure of defendants to explicitly say so -- assuming they did fail to say so -- was not a material omission in the context of the total mix of available

information.[4] Moreover, the new alleged facts do not give rise to a "strong inference" of fraudulent intent. Kalnit v. Eichler, 264 F.3d 131, 138 (2d Cir. 2001); see Goplen v. 51job, Inc., 453 F. Supp. 2d 759, 770-71 (S.D.N.Y. 2006). The Supreme Court has held that for the inference of fraudulent intent to qualify as "strong," it must be more than merely plausible or reasonable -- it "must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 314 (2007). That is no longer the case here, with the original allegations in the complaint deleted and the new ones substituted in their place.

As for the second allegation that plaintiffs now acknowledge was false, they contend that,

> [i]f the [c]omplaint adequately identified material omissions with its claim that [d]efendants should have disclosed the FDA's lack of experience with the PFS endpoint in the generic sense, then it is equally misleading, as alleged in the [a]mended [c]omplaint, for [d]efendants not to disclose that the FDA had no experience [with] the PFS endpoint, as defined by [d]efendants.

(Pl. Leave Mem. 14). Again, I disagree. Lack of experience with an entire concept is fundamentally different from lack of experience with a particular iteration of that concept. In the complaint, plaintiffs alleged that the FDA was completely unfamiliar with PFS -- we know now that is untrue. The FDA was unfamiliar with GPC's particular version of PFS, not PFS as an

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[4] In fact, defendants point to public statements they made disclosing the risk that the FDA would deny final approval of Satraplatin. (Def. Mem. at 27-28 & n.14).

endpoint in a categorical sense. Obviously, there is a significant difference. Plaintiffs' allegation that the FDA had no experience with PFS as an endpoint supported plaintiffs' allegation that the FDA had not agreed to use of PFS as an endpoint. 597 F. Supp. 2d at 423-24. If, in fact, the FDA had no experience whatsoever with PFS as an endpoint, this is something defendants should have disclosed. That the FDA had experience with PFS as an endpoint, but just not GPC's particular iteration of PFS, is not something that would have reasonably altered the total mix of information available.

I conclude that amendment of the complaint would be futile, as the amended complaint, with the critical allegations deleted, would fail to sufficiently allege the elements of materiality and scienter.

CONCLUSION

For the reasons stated above, plaintiffs' motion for leave to amend the complaint is denied. The Clerk of the Court shall enter judgment dismissing the complaint, as set forth in the Court's order dated March 12, 2009, with prejudice and with costs, but without attorneys' fees. Defendants' request for sanctions is denied.

SO ORDERED.

Dated: New York, New York
December 29, 2009

DENNY CHIN
United States District Judge